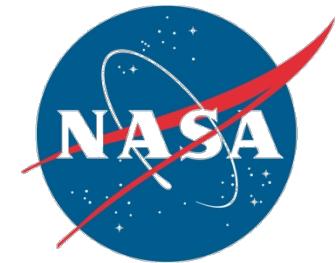


USE OF VARIABLE PRESSURE SUITS, INTERMITTENT RECOMPRESSION AND NITROX BREATHING MIXTURES DURING LUNAR EXTRAVEHICULAR ACTIVITIES



Michael L. Gernhardt, Ph.D.¹
Andrew F. J. Abercromby, Ph.D.²

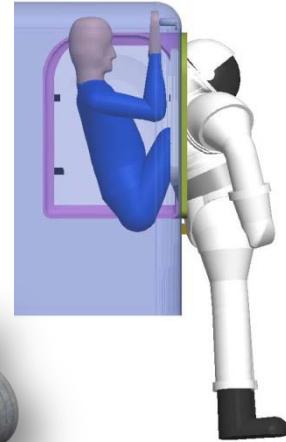
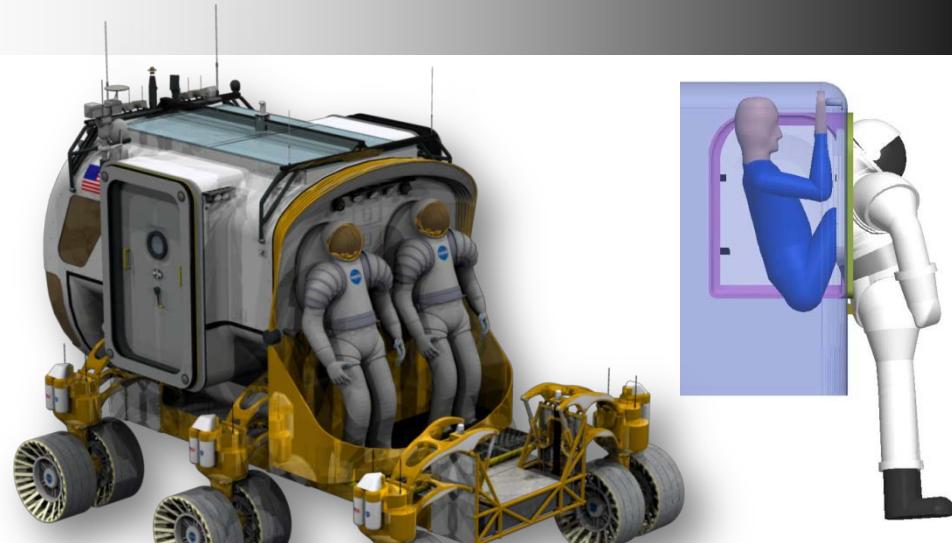
¹ NASA Johnson Space Center, Houston, TX

² Wyle, Houston, TX



Lunar Electric Rover

- ◆ Current plans for lunar surface exploration include small pressurized rovers (“Lunar Electric Rovers”) that are quickly ingressed and egressed with minimal consumables losses
 - Cabin: 8 PSI, 32% O₂, 68% N₂
- ◆ This capability enables crew members to perform multiple short extravehicular activities (EVAs) at different locations in a single day versus a single 8-hr EVA
- ◆ The new operational concept of multiple short EVAs necessitates short purge times and short prebreathes to ensure rapid egress with minimal loss of consumables
- ◆ Preliminary analysis has begun to evaluate the potential benefits of intermittent recompression, variable pressure EVA suits and Nitrox breathing mixtures in enabling reduced purge and prebreathe durations





Suit Port Egress and Ingress Procedures

Egress Procedures

1. Don Suit (8.0 PSI)
2. Close/lock hatch (blue)
3. Mode to PRESS (6.0 PSI)
4. 2 min leak check in suit
5. Purge 2 min
6. Mode to EVA (6.0 PSI)
7. Start prebreathe clock
8. Vestibule depress to 3.5 PSI
9. Leak Check 1 min
10. Vestibule depress to 0.0 PSI
11. Release Suit Port (red)

Egress Time: 11 min ± 3 min

Depress suit to 4.3 PSI 15 mins after start of prebreathe clock



Ingress Procedures

1. Engage Suit Port (red)
2. Vestibule press to 8.0 PSI
3. Leak Check 1 min
4. Vestibule-Cabin press equalization
5. Vestibule-Cabin-Suit equalization
6. Open PLSS lock
7. Open hatch (blue)
8. Close PLSS lock
9. Egress suit

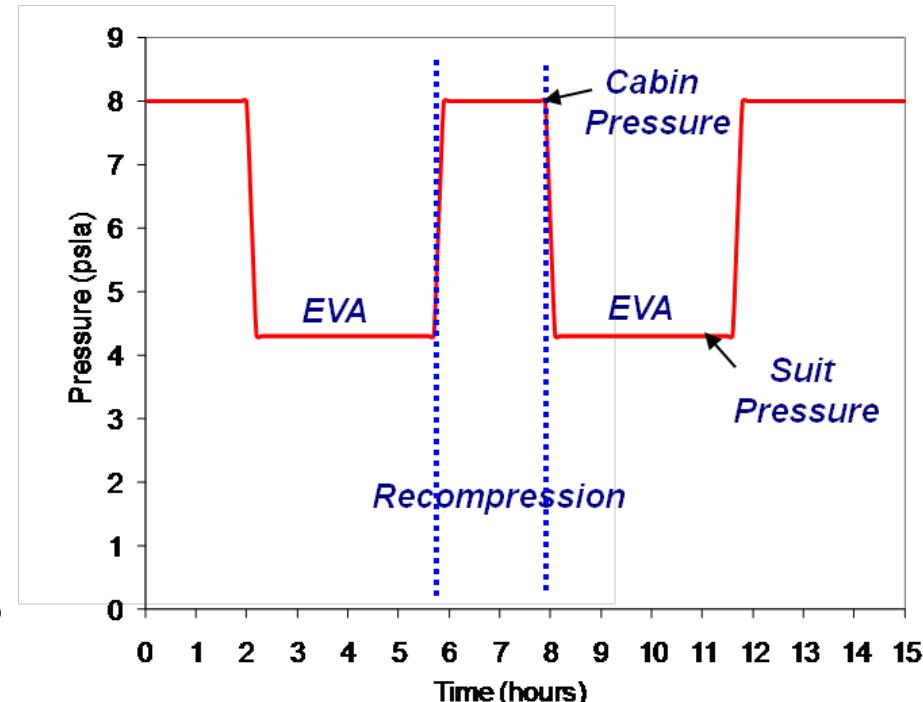
Ingress Time: 5 min ± 1 min





Intermittent Recompression

- ◆ Intermittent Recompressions (IR) during saturation decompression previously proposed as a method for decreasing decompression stress and time
(Gernhardt, 1988)
 - Gas bubbles respond to changes in hydrostatic pressure on a time scale much faster than the tissues
- ◆ Previous modeling work and empirical human and animal data indicate that IR between EVA suit pressure (≤ 4.3 psia, 100% O₂) and cabin pressure (8 psia, 32% O₂) may reduce decompression stress
- ◆ IR has been shown to decrease decompression stress in humans and animals *(Pilmanis et al. 2002, Møllerløkken et al. 2007)*
- ◆ During recompressions:
 - Reversed N₂ concentration gradient during recompression means that N₂ reuptake from blood into the tissues slowly begins
 - At the same time, increased hydrostatic pressure rapidly reduces the size of the bubbles such that the pressure due to surface tension inside the bubble increases, causing a higher bubble-to-tissue N₂ diffusion gradient
 - Because the volume of gas in the bubbles is small compared to the volume of gas in surrounding tissues, the N₂ elimination from the bubbles does not significantly increase N₂ tissue tension

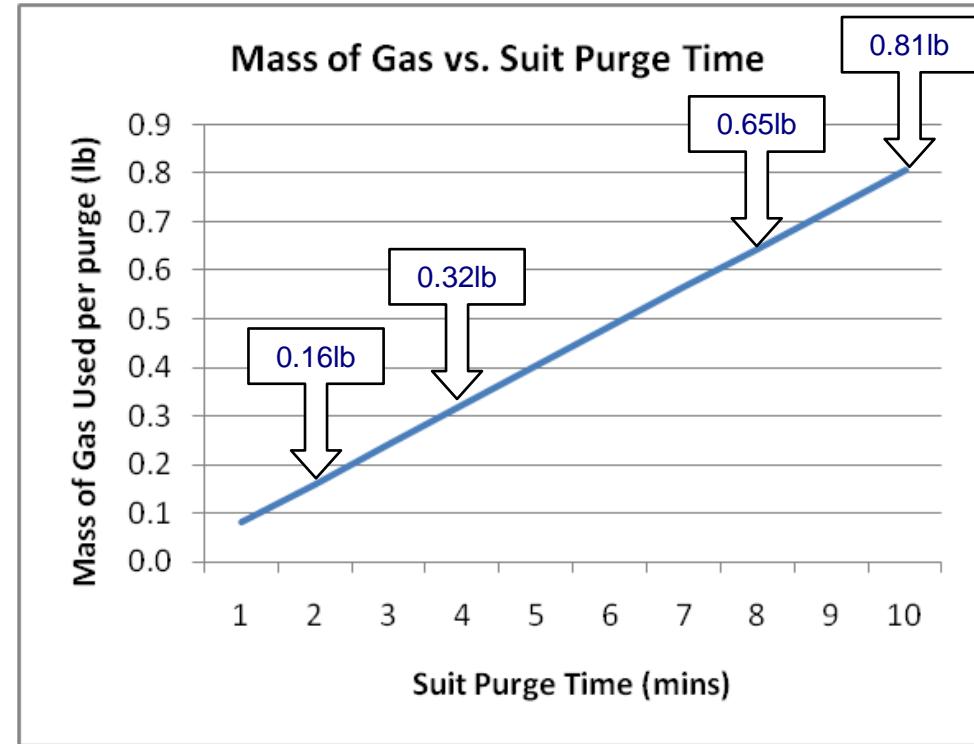




Abbreviated Suit Purge: Mass and Time Savings

- ◆ EVA suits are purged of N₂ prior to depressurization to achieve $\geq 95\%$ O₂
 - Purge requires ~ 8 minutes and uses 0.65 lb gas per purge per suit
- ◆ In an airlock, most of this gas is reclaimed but with a suit port this gas is vented to vacuum
 - Shortening the purge will expedite vehicle egress & save gas
- ◆ A 2 min purge saves ~ 0.48 lb gas and 6 minutes of crew time per person per egress compared with a standard 8 min purge

Cumulative Gas and Crew Time Saved by Abbreviated Purge



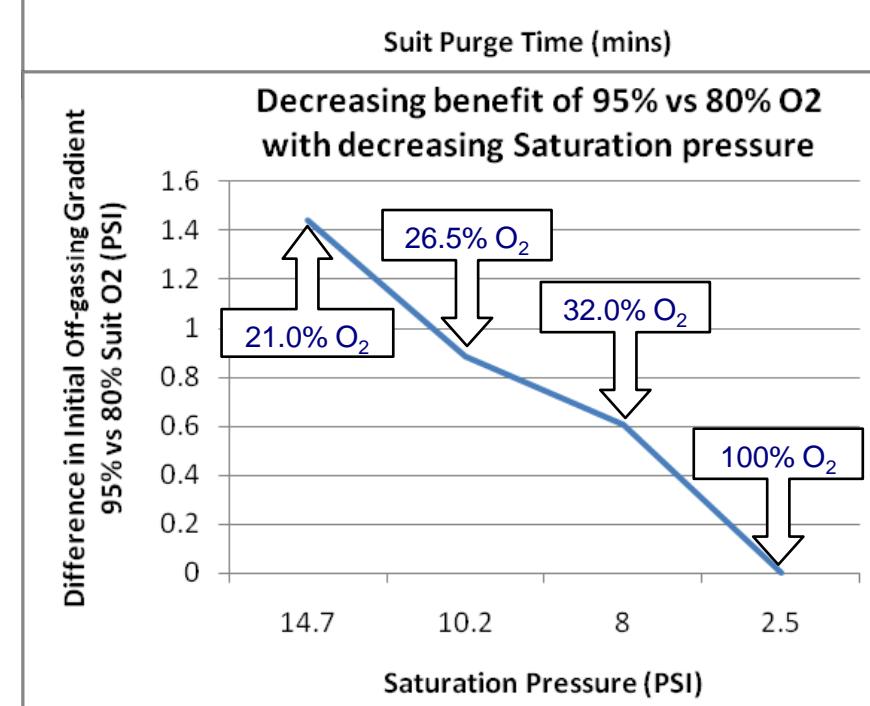
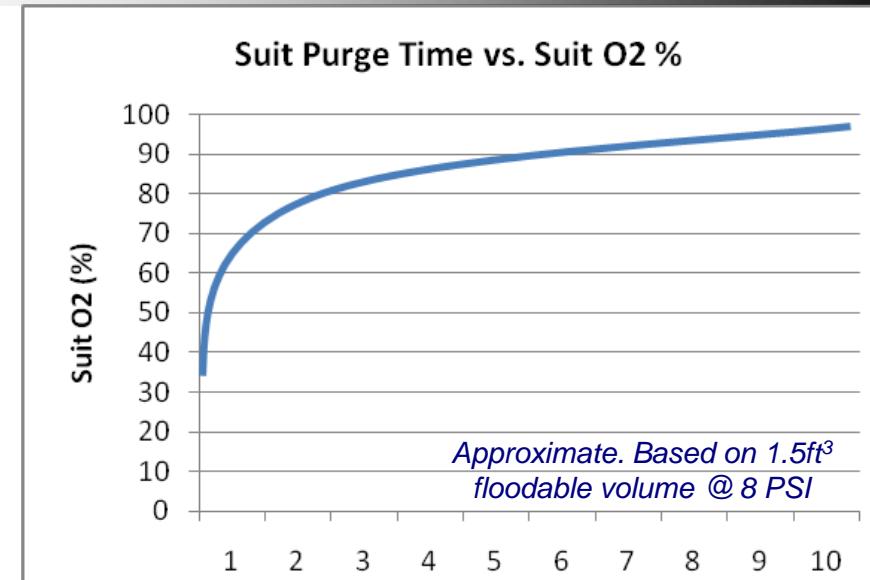
6 month mission, 4 crew, 3 egresses /day, 6 days/week:

- 900 lb gas + tankage = 1800 lb (819 kg)
- Over 31 hours of crew time saved



Abbreviated Suit Purge: Decreased Off-Gassing Gradient

- ◆ As described, an abbreviated purge saves gas and crew time, but decreases the N_2 off-gassing gradient because suit O_2 reaches only 80% compared with 95% O_2 achieved during an 8 minute purge
- ◆ However, the benefit of 95% O_2 vs. 80% O_2 for denitrogenation is reduced when initial saturation pressure is 8 PSI (LER) vs. 14.7 PSI (ISS) as there is a smaller change in off-gassing gradient



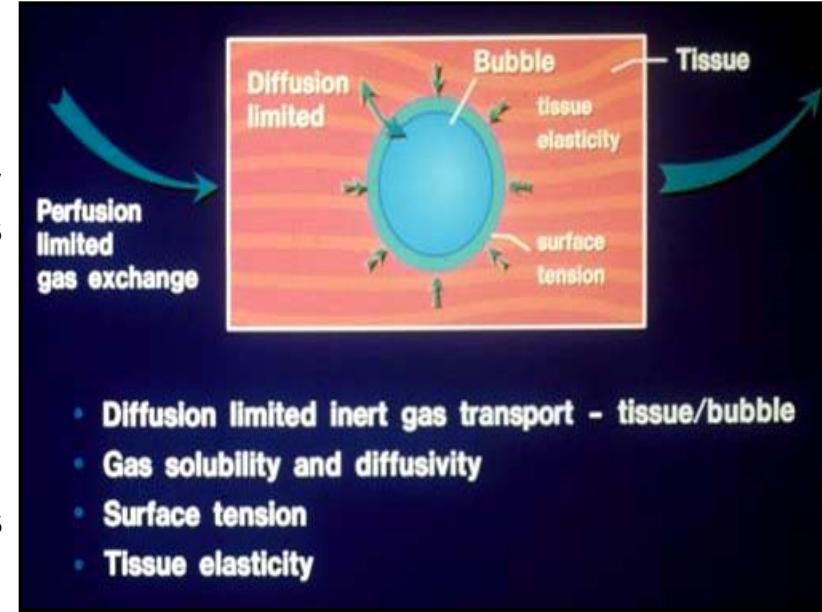


Tissue Bubble Dynamics Model (TBDM)

◆ Decompression stress index based on tissue bubble growth dynamics

(Gernhardt, 1991)

- Original statistical analysis of 6437 laboratory dives (430 DCS cases) compared predictions of the TBDM to Workman M-value and the Hempleman PrT index. TDBM predictions (Bubble Growth Index) yielded best log-Likelihood and Hosmer-Lemeshow Goodness-of-Fit Test
- Used operationally in more than 25,000 dives with extremely low DCS incidence (< 0.1%)



$$\frac{dR}{dt} = \frac{\alpha D}{h(r,t)} \left[P_a - vt + \frac{2\gamma}{r} + \frac{4}{3} \pi r^3 M - P_{\text{Total}} - P_{\text{metabolic}} \right] + \frac{rv}{3}$$

$$P_a - vt + \frac{4\gamma}{3r} + \frac{8}{3} \pi r^3 M$$

t = Time (sec)

a = Gas Solubility ((mL gas)/(mL tissue))

D = Diffusion Coefficient (cm²/sec)

h(r,t) = Bubble Film Thickness (cm)

P_a = Initial Ambient Pressure (dyne/cm²)

v = Ascent/Descent Rate (dyne/cm².cm³)

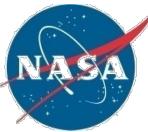
g = Surface Tension (dyne/cm)

M = Tissue Modulus of Deformability (dyne/cm².cm³)

P_{Total} = Total Inert Gas Tissue Tension (dyne/cm²)

P_{metabolic} = Total Metabolic Gas Tissue Tension

Data Set: In-Water Decompression on Air		Test for Improvement		Test for Goodness of Fit	
Index	Log-Likelihood	x ²	p-value	x ²	p-value/df
Null set	-529	n/a	n/a	n/a	n/a
Bubble Growth Index	-498	62.8	<0.001	4.8	0.77/8
Relative Super-saturation	-524	10.8	.001	19.4	0.08/12
Exposure Index	-505	47.9	<0.001	30.5	0.00/9



Tissue Bubble Dynamics Model (TBDM)

◆ Logistic Regression

- Logistic regression quantitatively relates the TBDM Bubble Growth Index (BGI) to a % DCS risk based on existing altitude DCS data
- Performed using DCS and VGE data from NASA Bends Tests 1-7
 - n=345, 57 DCS cases
 - 16.5% DCS, 41.4% VGE
- Prebreathe staged decompressions, all with exercise at altitude and includes data points at 10.2, 6.0, and 4.3PSI
- Does not include adynamic data
- BGI provided significant prediction of DCS and VGE data ($p < 0.01$)
- Hosmer-Lemeshow Goodness-of-Fit statistic: $p=.35$ for DCS, $p=.55$ for VGE, indicating a good fit of the data
 - For Hosmer-Lemeshow statistic, $p > .05$ rejects the hypothesis that there is a significant difference between the model predictions and the observed data



Objectives & Methods

- ◆ **Part I:** Compare super-saturation in the brain and spinal cord (5 and 10 minute half-time compartments) and tissue tensions in 40 minute compartments, where most of the body's inert gas is located, for the following conditions:
 - 15-minute 80% O₂, 20% N₂ prebreathe @ 6.0 PSIA , Sat @ 8.0 PSI, 32% O₂, 68%N₂
 - 40-minute 95% O₂, 5% N₂ prebreathe @ 10.2 PSIA , Sat @ 10.2 PSI, 26.5% O₂, 73.5%N₂
- ◆ **Part II:** Use TBDM to estimate DCS Risk under the following scenarios:
 - Purge cases:
 - 8 minute, 95% O₂ suit purge
 - 2 minute, 80% O₂ suit purge
 - EVA cases:
 - 3 x 2 hr EVAs separated by 60 min at cabin pressure (8 PSI, 32% O₂, 68% N₂)
 - 1 x 8 hr EVA
- ◆ **Assumptions:**
 - Crew begin saturated at 8 PSI, 32% O₂ / 68% N₂
 - Purge performed at 8 PSI
 - 1 minute post-purge depress to 6 PSI
 - 15 minutes prebreathe completed at 6 PSI (EVA may begin during this time)
 - Depress to 4.3 PSI at 5,000 FPM after 15 min at 6.0 PSI
 - Repress from 4.3 PSI to 6.0 PSI at 5,000 FPM



Results: Part I

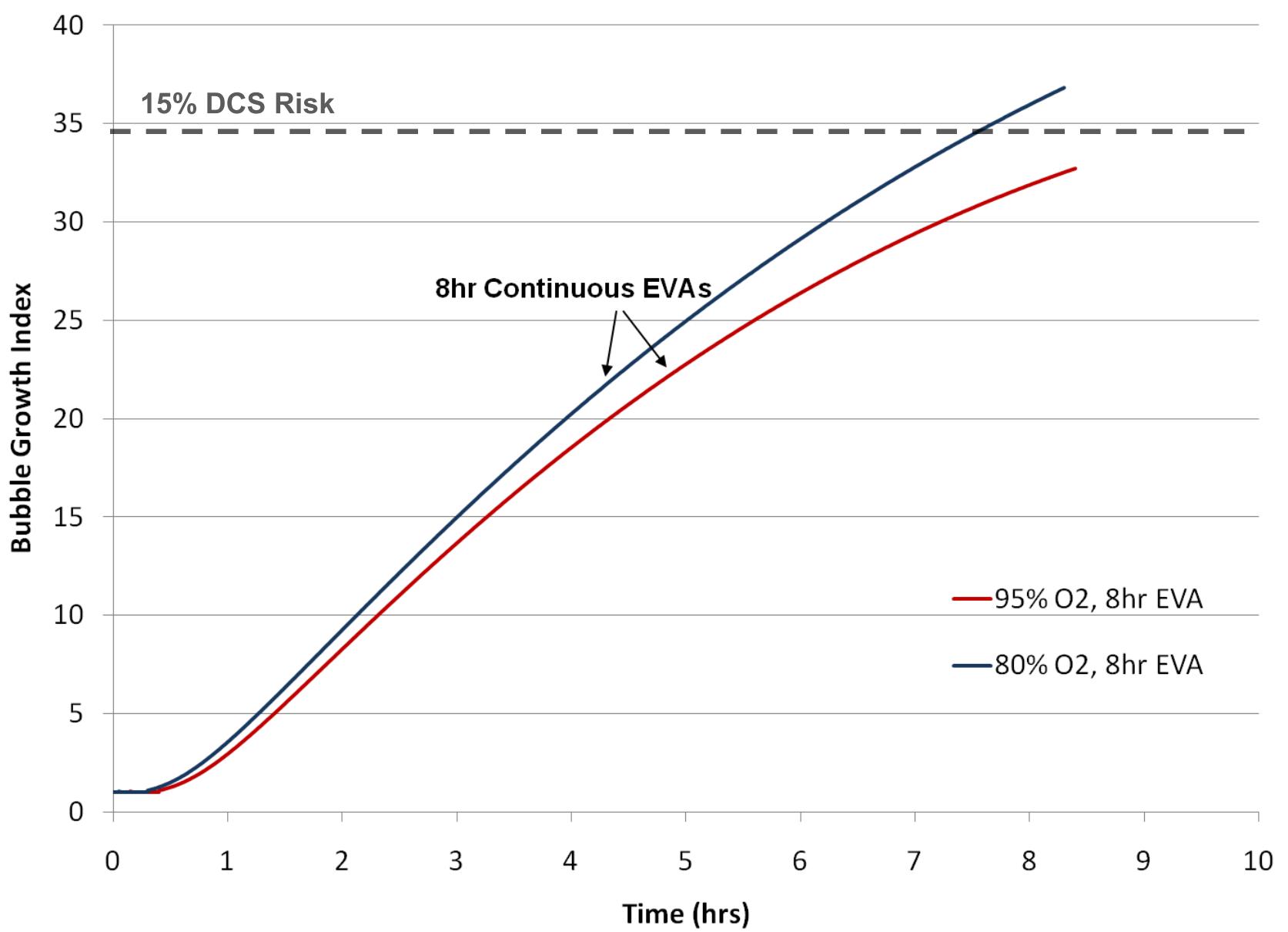
Comparison of 15 minute 80% O₂ 6.0 PSI prebreathe vs. 40 minute 95% O₂ 10.2 PSI prebreathe

- ◆ **5- and 10-min Tissues (brain and spinal cord):**
 - Supersaturation eliminated
- ◆ **40 min Tissues (most of body's inert gas):**
 - 4.0 PSI after 40 minutes @ 95% O₂
 - 4.37 PSI after 15 minutes @ 80% O₂ (incl. 2 min purge and 1 min depress)

→ 15 minute 80% O₂ prebreathe eliminates CNS supersaturation and provides N₂ elimination approximately equivalent to standard 40 min 95% O₂ prebreathe from 10.2 PSI.

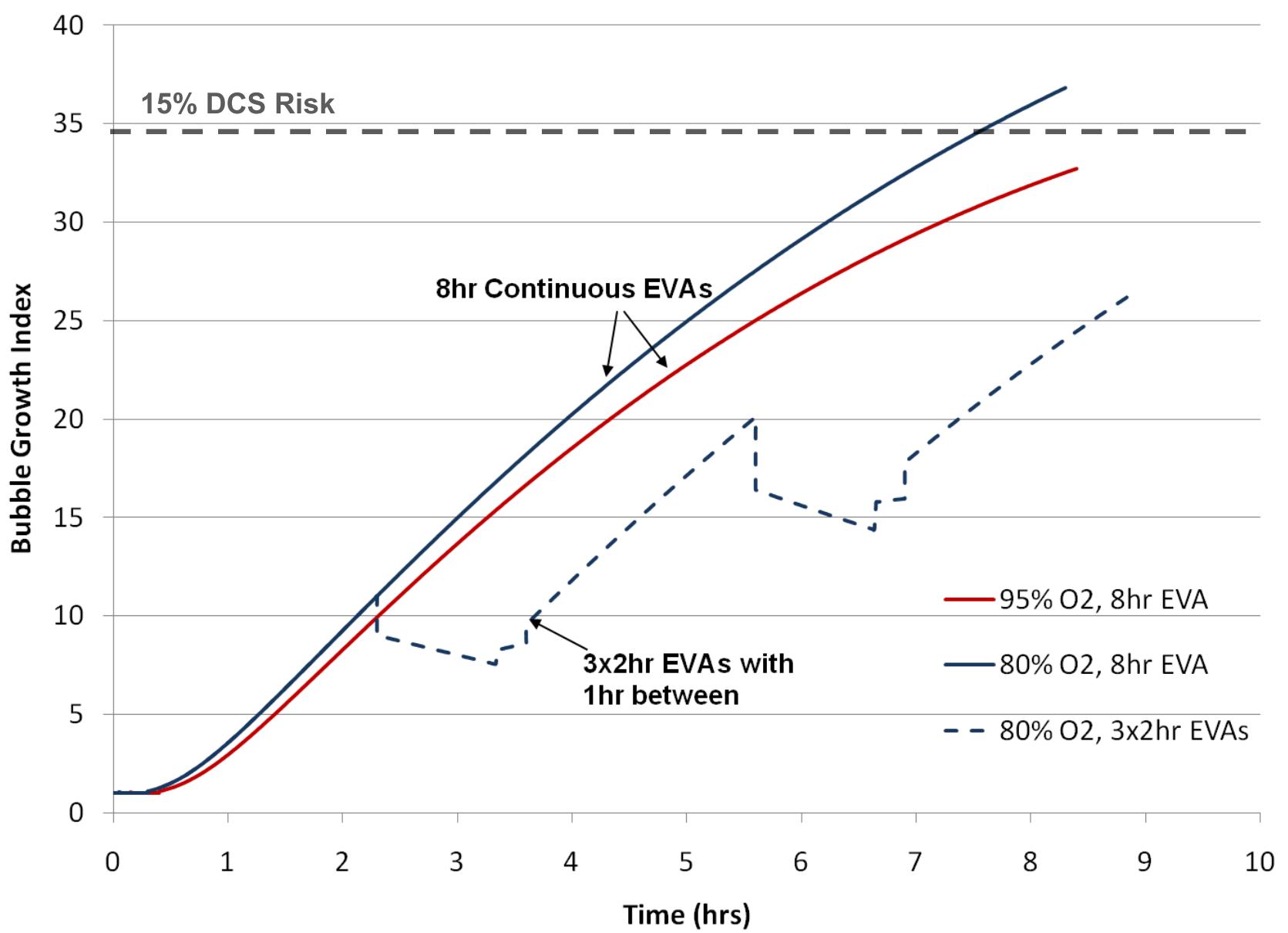


Results: Part II





Results: Part II





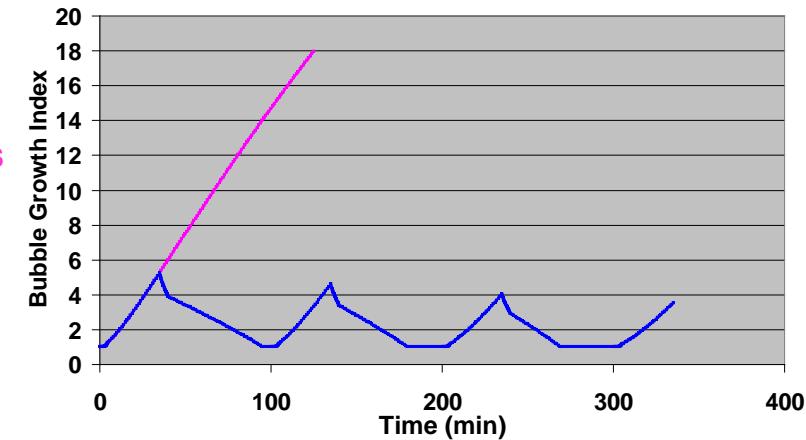
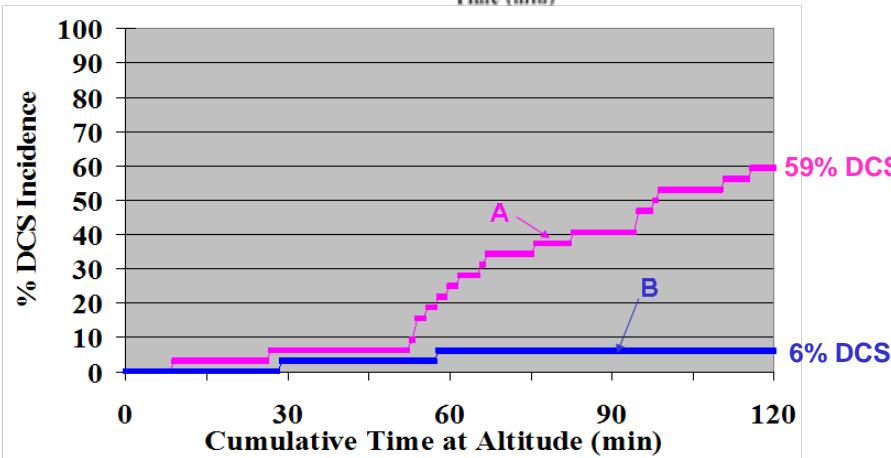
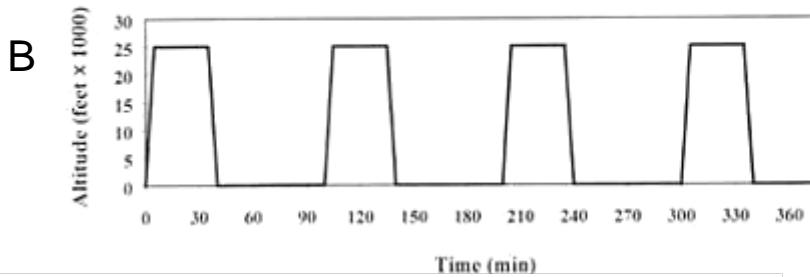
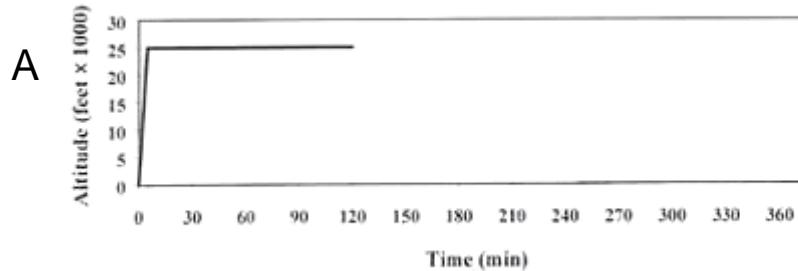
Discussion

- ◆ In this analysis:
 - 80% O₂ vs. 95% O₂ during an 8-hr continuous EVA increased DCS Risk by 2.2%
 - 1 hr Recompressions between 3x2 hr EVAs performed with 80% O₂ reduced decompression stress by 2.8% compared with an 8-hr continuous EVA with 95% O₂
- ◆ Intermittent recompressions reduce decompression stress by limiting the bubble growth time and size, resulting in a higher bubble to tissue diffusion gradient due to the effects of surface tension (Laplace's Law)
- ◆ Recent analog field test data demonstrated that crewmembers performing multiple EVAs from an LER achieved 57% greater performance while using 61% less EVA time than when performing continuous EVAs using an unpressurized rover
 - Actual decompression benefits of LERs may be even more significant
- ◆ In case an EVA lasts longer than planned, variable pressure suits will allow an in-suit intermittent recompression back to 6 PSI without ingressing the LER. Supplemental suit purge (increased suit O₂ %) could also be performed.
- ◆ At 80% O₂, 4.3 PSIA crewmembers will be hyperoxic. In the event of a suit leak, the Secondary Oxygen Pack (SOP) will maintain the suit at ~3.6 PSI making crew only mildly hypoxic (2.9 PSI ppO₂) but still maintaining a higher ppO₂ than the nominal cabin environment (2.4-2.6 PSI ppO₂)



Discussion

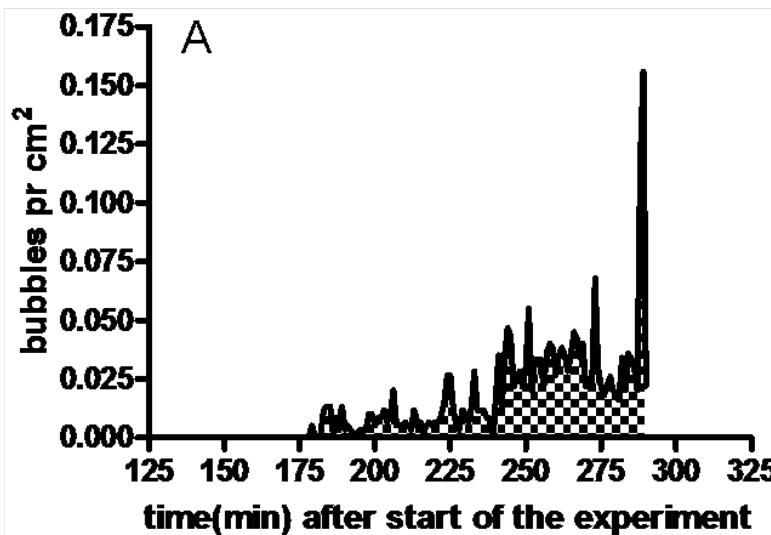
A. One 2-h exposure, no preoxygenation



Pilmanis A.A., Webb J.T., Kannan N., Balldin U. The effect of repeated altitude exposures on the incidence of decompression sickness. Aviat Space Environ Med; 73: 525-531, 2002.

Discussion

Without Intermittent Recompression



With Intermittent Recompression

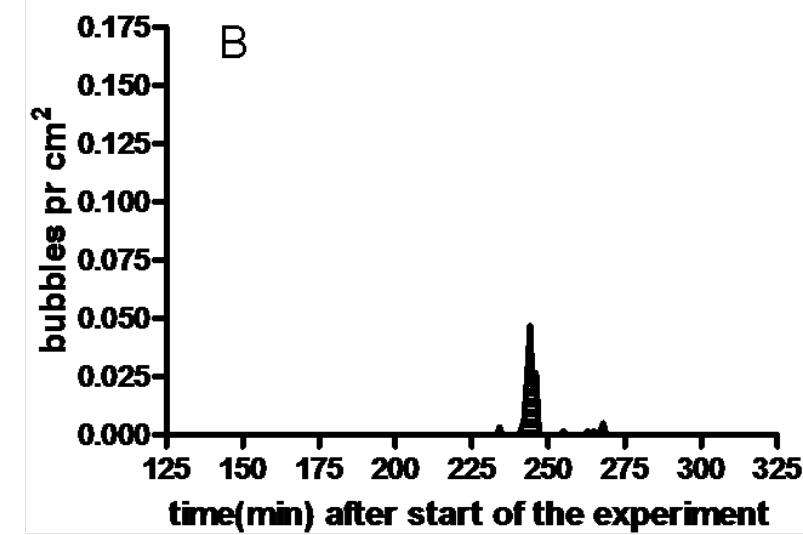
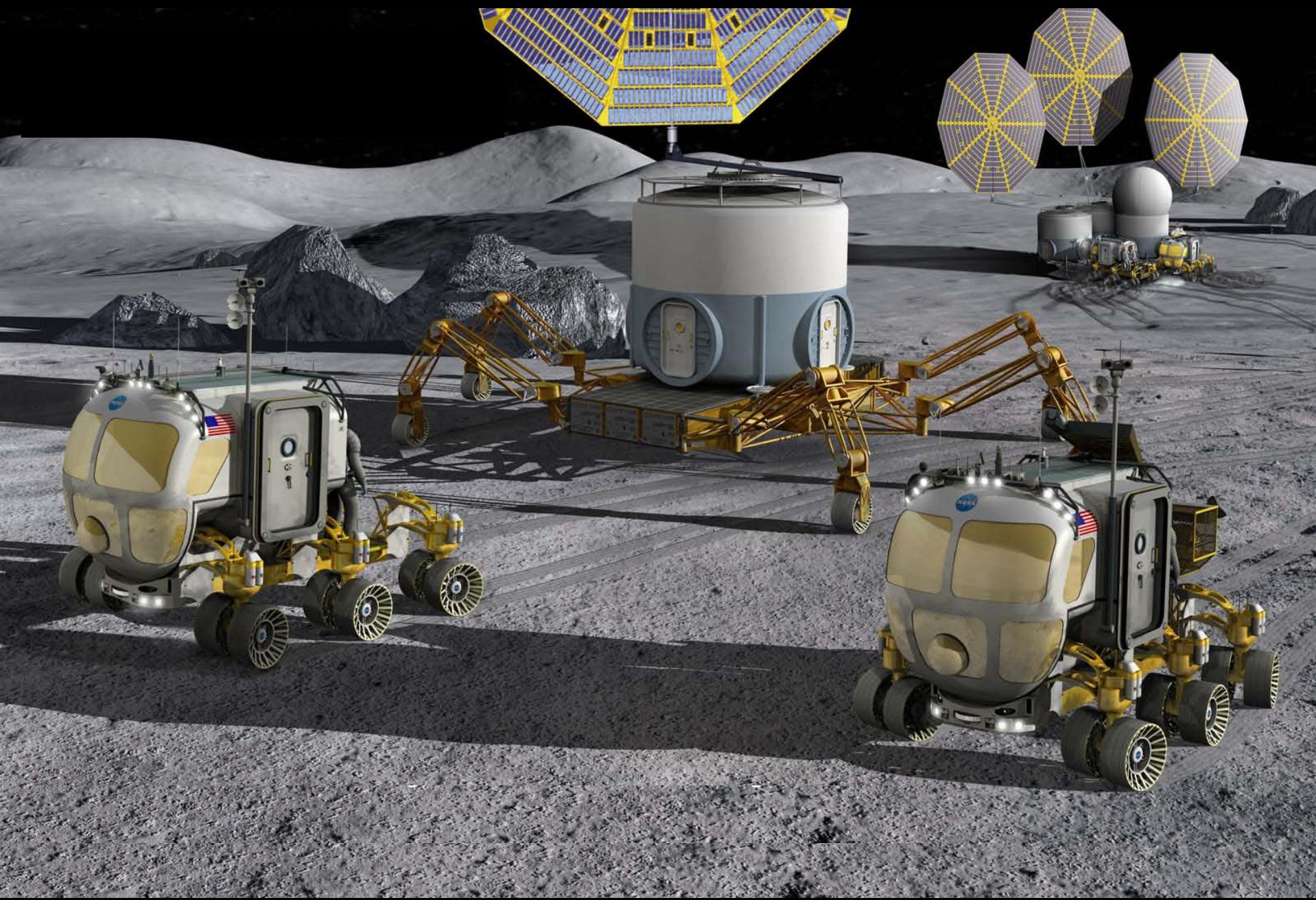


Fig. 10. Two groups of six pigs were compressed to 121 FSW with 90 minutes bottom time and were then decompressed following one of two decompression procedures; either with a 5-min 12 FSW recompression at the end of the three last decompression stops (experimental group), or without such recompression (control group). The control profile was a USN profile for this exposure, where the stop times were reduced by 50% as pilot studies showed that the standard USN profile produced very few bubbles. The average number of venous gas bubbles measured in the pulmonary artery during the decompression is shown for the control group (A) and the experimental group (B). The results indicate significantly fewer bubbles in the experimental group than in the control group ($p<.0001$). *From Møllerløkken et al. (5) by permission.*



Conclusions

- ◆ Variable pressure suits combined with the ability to perform multiple, shorter EVAs may enable prebreathe protocols that save several tons of gas and hundreds of hours of crew time over the duration of the next lunar program
- ◆ Further research is needed to characterize and optimize intermittent recompression and Nitrox breathing mixtures across the range of environments and operational conditions in which astronauts will live and work during future lunar exploration
- ◆ Laboratory validation trials should precede operational implementation



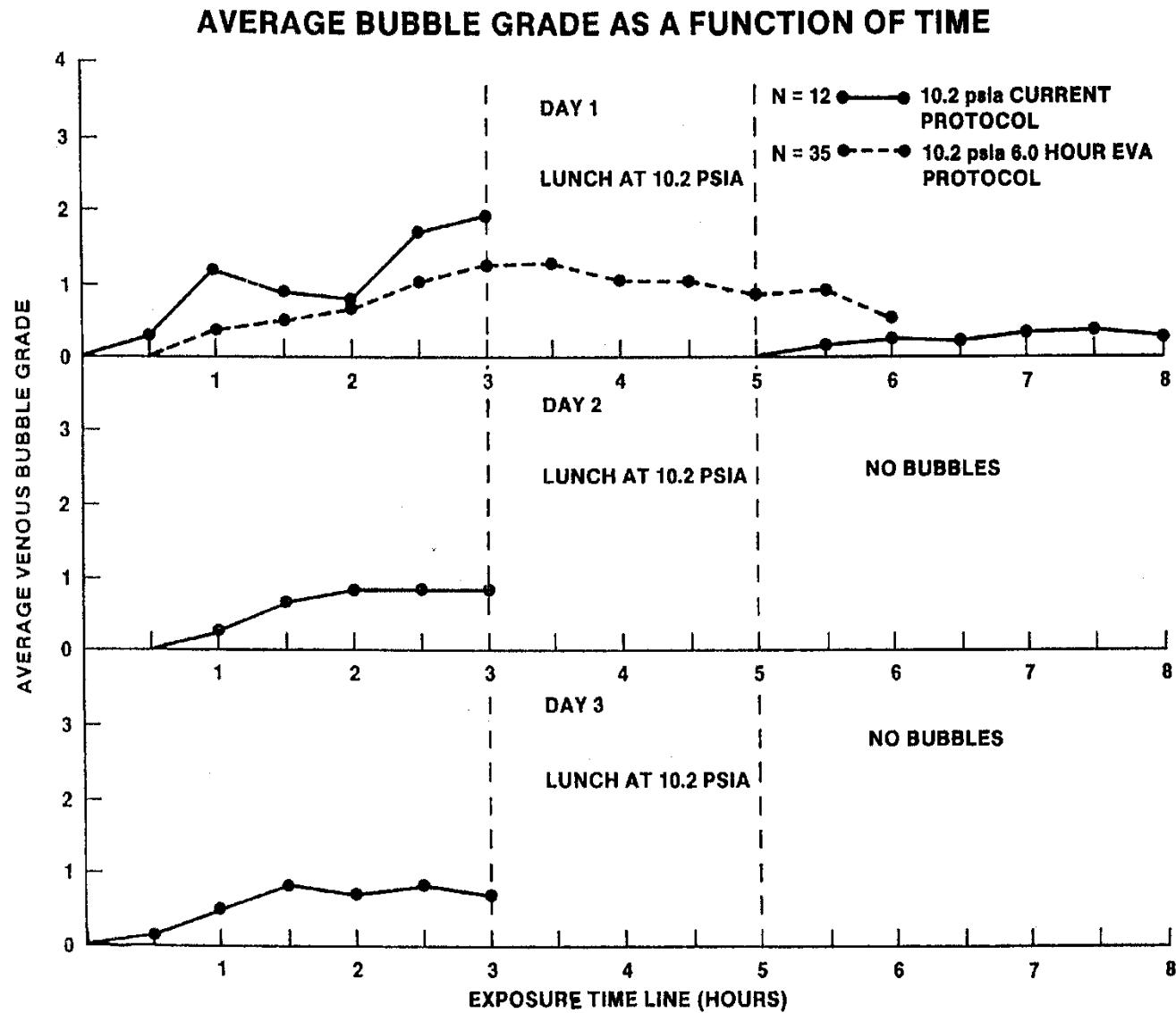


Backup

- ◆ **45 min additional time (i.e. 60 min total) at 6.0 PSI required at beginning of first EVA only**
 - 45 min also required to match P(DCS) for continuous 8hr EVAs
- ◆ **Or, 35 min additional time at 6.0 PSI required prior to all EVAs**



Repetitive EVAs





Intermittent Recompression, Bubble Model incorporating Hill's Assumption of Profuse Tissue Bubble Nucleation

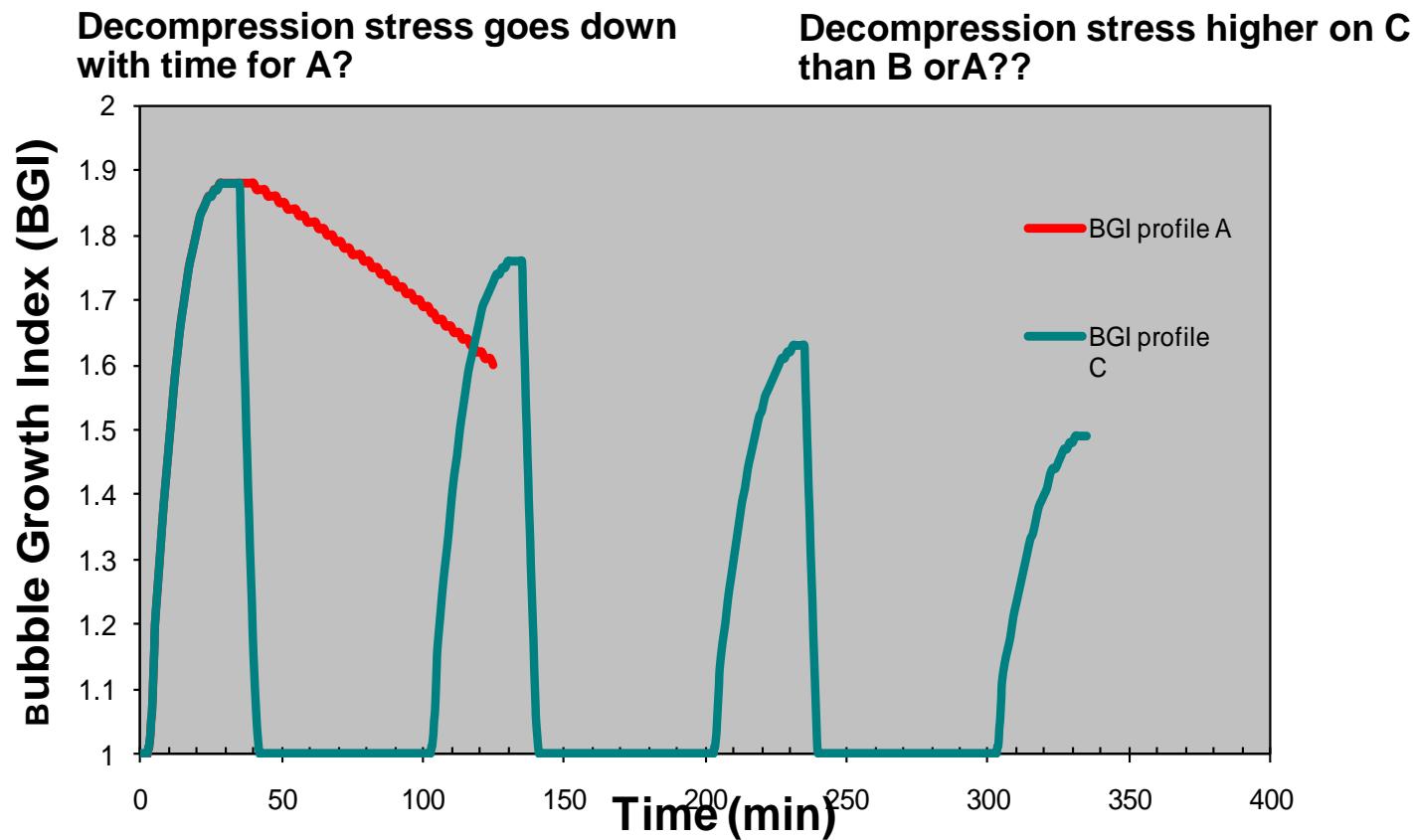


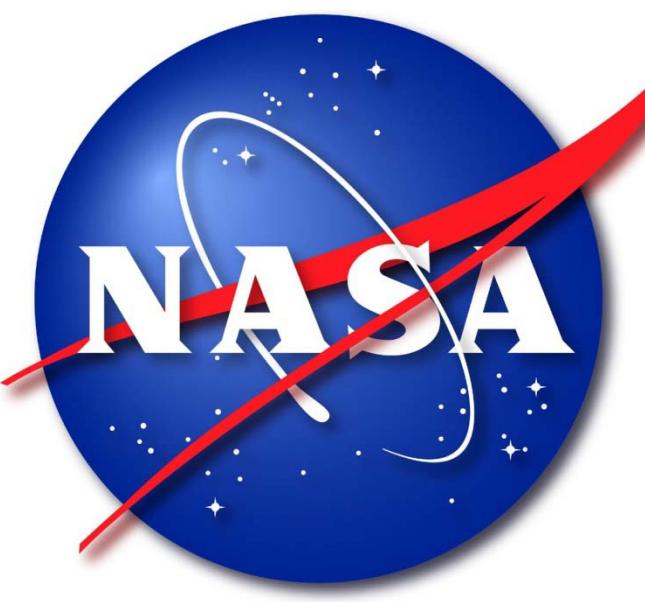
Fig. 4. Exposures A,C with high tissue bubble density and mass balance.



DCS and VGE Incidence from Repetitive EVA Exposure

		First 3 hr test at 4.3 psia				Second 3 hr test at 4.3 psia			
	TR360	DCS	VGE	Grades	TR360	DCS	VGE	Grades	
Day 1	1.68	1/12	7/12	2,2,3,4, 4,4,2	1.12	0/12	2/12	4,1	
Day 2	1.37	0/12	4/12	3,3,2,4	0.95	0/12	0/12	all 0	
Day 3	1.35	0/12	4/12	3,3,2,4	0.94	0/12	0/12	all 0	

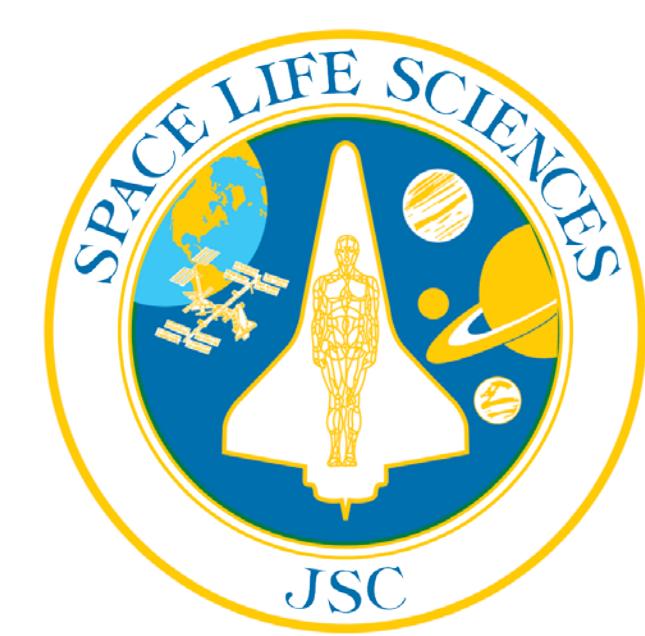
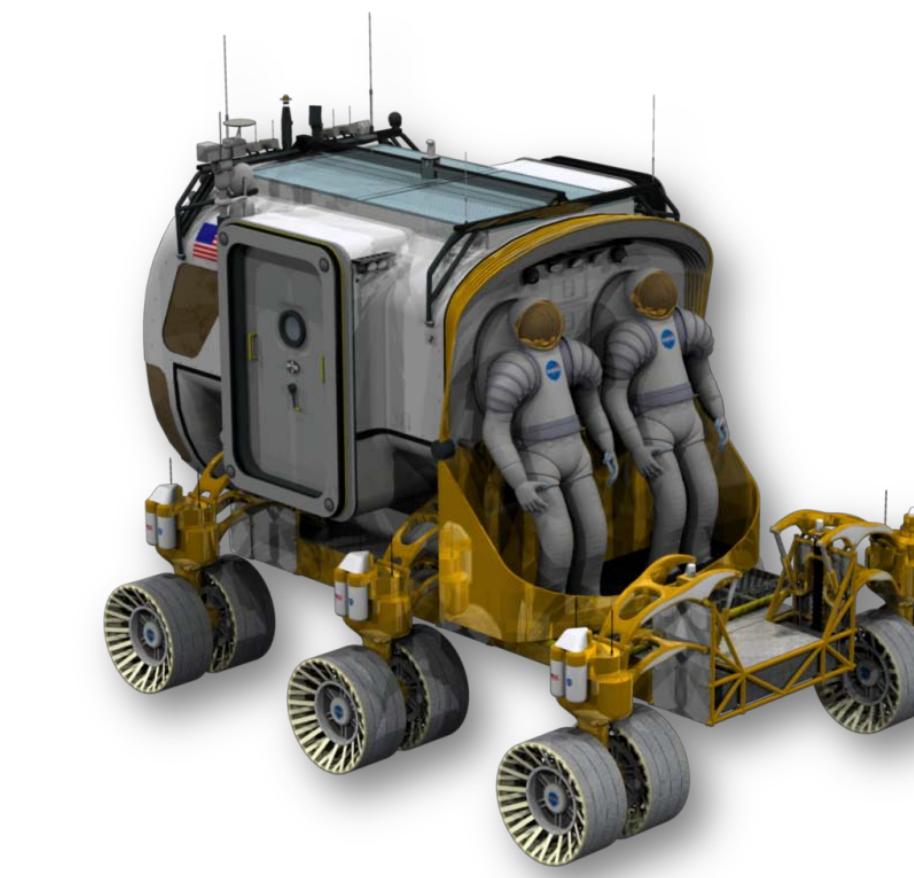
Unlike repetitive diving, repetitive EVA results in lower decompression stress



USE OF VARIABLE PRESSURE SUITS, INTERMITTENT RECOMPRESSION AND NITROX BREATHING MIXTURES DURING LUNAR EXTRAVEHICULAR ACTIVITIES

Michael L. Gernhardt, Ph.D.¹, Andrew F. J. Abercromby, Ph.D.²

¹ NASA Johnson Space Center, Houston, TX 77058. ² Wyle, Houston, TX 77058.



INTRODUCTION

- NASA's plans for lunar surface exploration include small pressurized rovers ("Lunar Electric Rovers") at 8.0 PSIA, 32% O₂, 68% N₂ with suit ports that enable rapid ingress and egress with minimal gas losses. This capability enables crewmembers to perform multiple short extravehicular activities (EVAs) at different locations in a single day versus a single 8-hr EVA. Development and validation of a prebreathe protocol that reduces the risk of decompression sickness (DCS) risk to within acceptable levels while preserving rapid egress capability is an essential component of the entire LER concept.
- Modeling work (1,2) and empirical human (3) and animal (4) data indicate that these intermittent recompressions between EVA suit pressure (4.3 PSIA) and cabin pressure (8 PSIA) reduce decompression stress.
- Typical 8-min suit purges, to achieve 95% O₂ suit breathing mixture, result in significant gas losses and unproductive crew time. A 2-min purge to ~80% O₂ addresses these issues but may increase DCS risk.
- An analysis using the Tissue Bubble Dynamics Model (5) was conducted to determine whether the increase in decompression stress resulting from an abbreviated suit purge would be offset by the decrease in decompression stress offered by intermittent recompression.

METHODS

- A validated Tissue Bubble Dynamics Model (TBDM) was used to predict DCS risk using 80% and 95% O₂ breathing mixtures during three 2-hr EVAs (4.3 PSIA) separated by 1-hr recompressions to cabin pressure (for driving between EVA sites) versus a single 8-hr EVA.
- Part I: Experience from altitude DCS suggests that some degree of enriched O₂ prebreathing is necessary to reduce the risk of central neurological DCS. The objectives of Part I of the analysis were i) to ensure that the proposed LER prebreathe protocol would eliminate super-saturation in the neurological tissues (brain and spinal cord, half-times approx. 5 - 10 minutes), and ii) to compare tissue tensions in ≤40 minute compartments, where the majority of whole-body nitrogen is located, with an established Shuttle staged prebreathe protocol in which no DCS cases have been reported.
 - LER Protocol: 15-minute 80% O₂, 20% N₂ @ 6.0 PSIA, Sat @ 8.0 PSI, 32% O₂, 68% N₂
 - Shuttle Protocol: 40-minute 95% O₂, 5% N₂ @ 10.2 PSIA, Sat @ 10.2 PSI, 26.5% O₂, 73.5% N₂
- Part II: The objective of Part II was to use the Tissue Bubble Dynamics Model (TBDM) (5) to estimate DCS Risk under the following scenarios:

Purge cases:

- 8 minute, 95% O₂ suit purge
- 2 minute, 80% O₂ suit purge

EVA cases:

- 3 x 2 hr EVAs separated by 60 mins at cabin pressure (8 PSI, 32% O₂ / 68% N₂)
- 1 x 8 hr EVA

The following assumptions were made:

- Crew begin saturated at 8 PSI, 32% O₂ / 68% N₂
- Purge performed at 8 PSI
- 1 minute post-purge depress to 6PSI
- 15 minutes prebreathe completed at 6 PSI (EVA may begin during this time)
- Depress to 4.3 PSI at 5,000 FPM after 15 mins at 6.0 PSI
- Repress from 4.3 PSI to 6.0 PSI at 5,000 FPM

- The TBDM model provides significant prediction ($p < 0.001$) and goodness of fit with 430 cases of DCS in 6437 laboratory dives (Table 1) and has been used operationally in over 25,000 dives.

Tissue Bubble Dynamics Model (TBDM) (5)

Bubble Growth Equation:

$$\frac{dR}{dt} = \frac{-\alpha D}{h(r,t)} \left[P_a - vt + \frac{2y}{r} + \frac{4}{3} \pi r^3 M - P_{\text{Total}} - P_{\text{metabolic}} \right] + \frac{rv}{3}$$

r = Bubble Radius (cm)

t = Time (sec)

α = Gas Solubility ((mL gas)/(mL tissue))

D = Diffusion Coefficient (cm²/sec)

h(r,t) = Bubble Film Thickness (cm)

P_a = Initial Ambient Pressure (dyne/cm²)

v = Ascent/Descent Rate (dyne/cm²·cm⁻³)

y = Surface Tension (dyne/cm)

M = Tissue Modulus of Deformability (dyne/cm²·cm⁻³)

P_{Total} = Total Inert Gas Tissue Tension (dyne/cm²)

P_{metabolic} = Total Metabolic Gas Tissue Tension



Fig. 1. Prototype LER suit ports being developed by NASA. The LER rover concept relies heavily on safe and efficient suit purge and prebreathe protocols to minimize gas losses and enable rapid vehicle egress.

- Logistic regression was used to quantitatively relate the TBDM Bubble Growth Index (BGI) to a % DCS risk based on existing altitude DCS data. The Logistics Regression was performed using DCS and VGE data from NASA Bends Tests 1-7 (n=345, 57 DCS cases, 16.5% DCS, 41.4% VGE). All data included prebreathe staged decompressions, all with exercise at altitude and included data points at 10.2, 6.0, and 4.3 PSI. No adynamic data were included.
 - BGI provided significant prediction of DCS and VGE data ($p < 0.01$)
 - Hosmer-Lemeshow Goodness-of-Fit statistic: $p=.35$ for DCS, $p=.55$ for VGE, indicating a good fit of the data (for Hosmer-Lemeshow statistic, $p > .05$ rejects the hypothesis that there is a significant difference between the model predictions and the observed data).

RESULTS

Part I: Comparison of 15 minute 80% O₂ 6.0 PSI prebreathe with 40 minute 95% O₂ 10.2 PSI Prebreathe

- 5- and 10-min Tissues (brain and spinal cord):
 - Supersaturation eliminated
- 40 min Tissues (most of body's inert gas):
 - 4.00 PSI after 40 minutes @ 95% O₂
 - 4.37 PSI after 15 minutes @ 80% O₂ (incl. 2min purge and 1 min depress)

- Fifteen minutes at 80% O₂, 6.0 PSIA, before a 4.3 PSIA EVA prevents supersaturation in the brain and spinal cord (5- and 10-min half-time compartments) and reduces tissue tensions in fast half-time compartments (≤ 40 -min), where the majority of whole-body Nitrogen is located, to approximately the levels (4.37 vs. 4.00 PSIA) achieved during a standard Shuttle/ISS staged prebreathe protocol.

Part II: Comparison of DCS Risk for 80% O₂ with Intermittent Recompression vs. 95% O₂ Continuous EVA

- 80% O₂ vs. 95% O₂ during an 8-hr continuous EVA increased DCS Risk by 2.2%
- 1hr Recompressions between 3x2hr EVAs performed with 80% O₂ reduced decompression stress by 2.8% compared with an 8-hr continuous EVA with 95% O₂

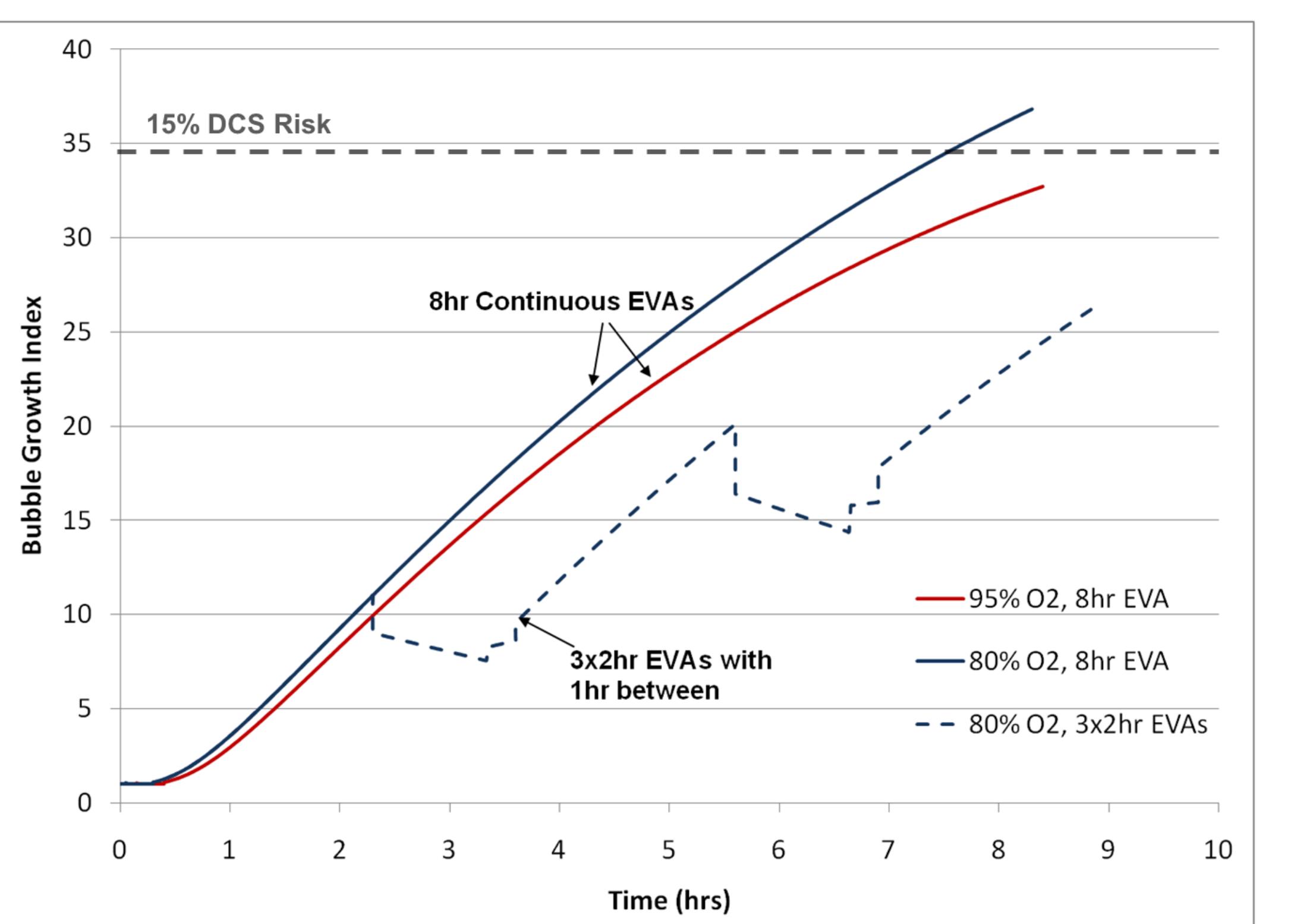


Fig. 2. (right) Theoretical decompression stress (Bubble Growth Index - BGI) comparison of 8hr continuous EVAs performed using 95% O₂ and 80% O₂. 3x2hr EVAs on 80% O₂ separated by 1hr intermittent recompressions are also shown, which reduced decompression stress below the 95% O₂ continuous EVA case and within the current definition of acceptable DCS risk.

- In the event that an EVA lasts longer than planned, variable pressure suits allow an in-suit intermittent recompression back to 6PSI without ingressing the LER. Supplemental suit purge (increased suit O₂ %) could also be performed.
- At 80% O₂, 4.3 PSIA crewmembers will be hyperoxic. In the event of a suit leak, the Secondary Oxygen Pack (SOP) will maintain the suit at ~3.6 PSI making crew only mildly hypoxic (2.9 PSI ppO₂) but still maintaining a higher ppO₂ than the nominal cabin environment (2.4-2.6 PSI ppO₂).
- An abbreviated purge decreases the N₂ off-gassing gradient because suit O₂ reaches only 80% compared with 95% O₂ achieved during an 8 minute purge (Fig. 3). However, the benefit of 95% O₂ vs. 80% O₂ for denitrogenation is reduced when initial is saturation pressure is 8 PSI (LER) vs. 14.7 PSI (ISS) as there is a smaller change in off-gassing gradient (Fig. 4).
- The TBDM predictions are based on the assumption that the volume of gas in the bubble is small compared to the volume of gas in surrounding tissue. This assumption is supported by experimental evidence from human (3) and animal (4) decompression trials. If tissues were profusely nucleated, resulting in many small bubbles, then tissue tensions would reduce as the bubbles grow, with the effect of decreasing off-gassing gradients. In this case, the larger quantity of gas in the numerous small bubbles would simply redistribute into the tissue during the recompression, resulting in an equivalent decompression penalty and no decompression benefit. However, the empirical data detailed in Figures 5-6 suggest that this is not the case.

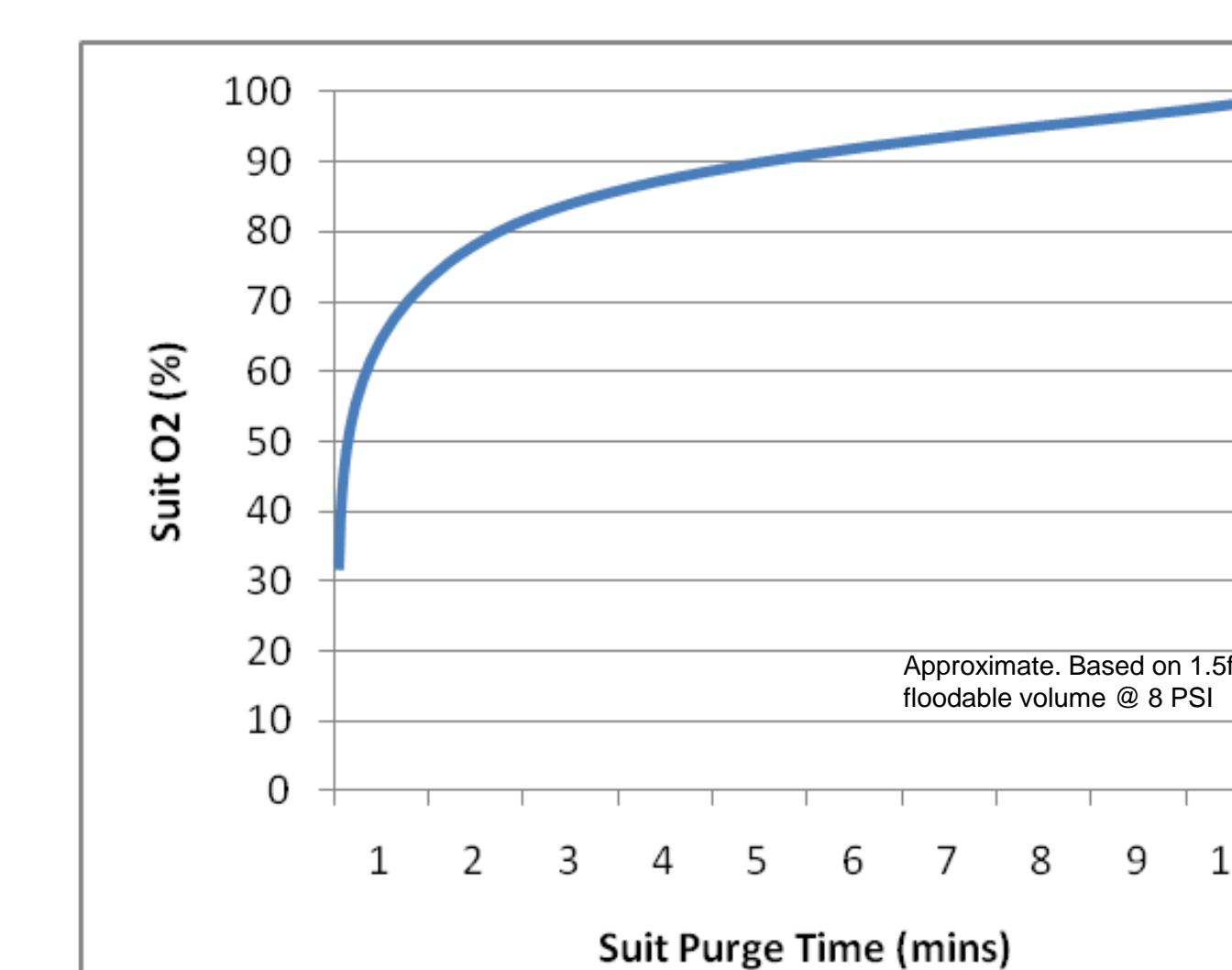


Fig. 3. Suit O₂ concentration as a function of suit purge time.

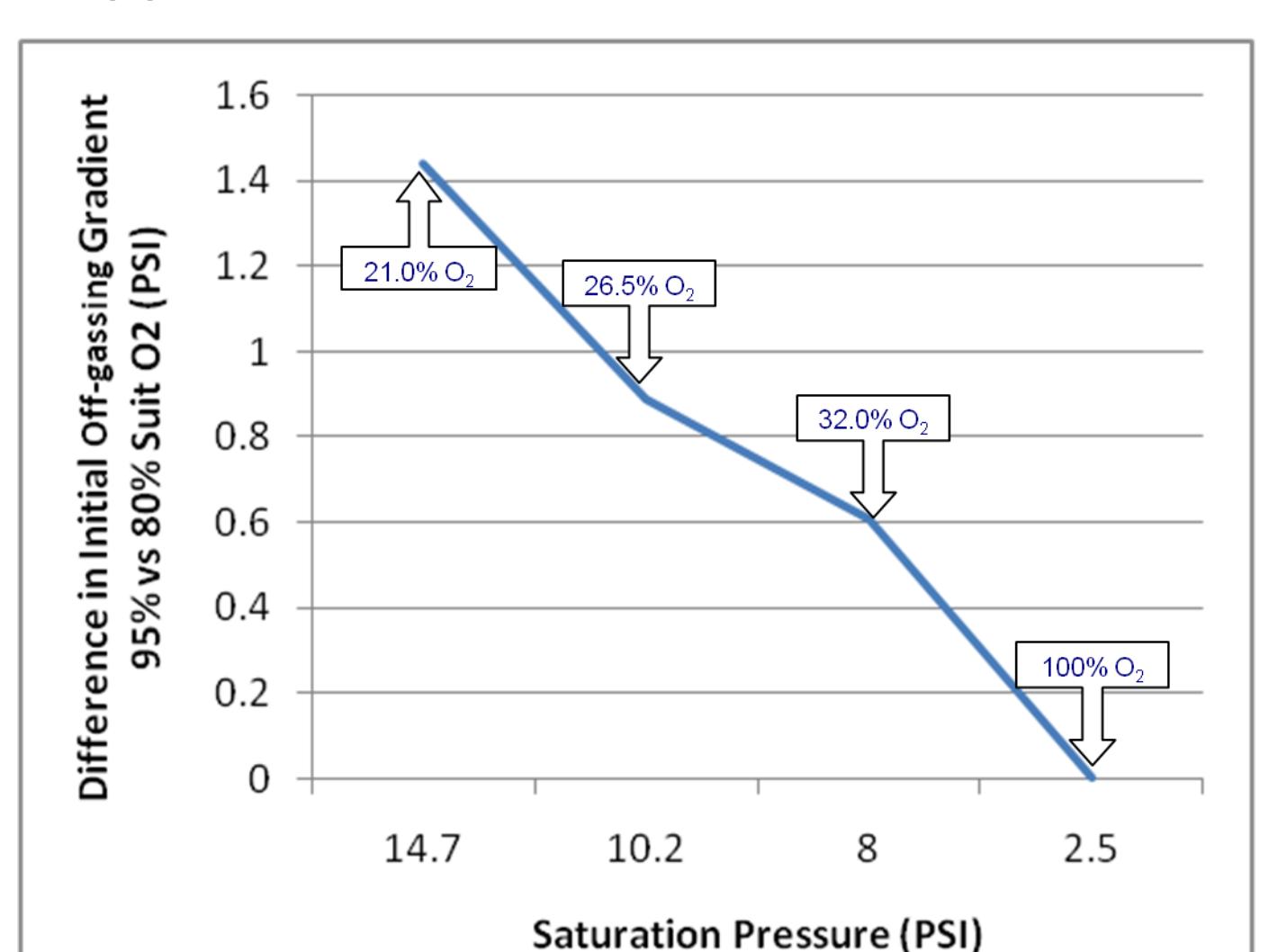


Fig. 4. Decreasing benefit of 95% vs. 80% O₂ prebreathe on initial N₂ off-gassing gradient as a function of decreasing saturation pressure.

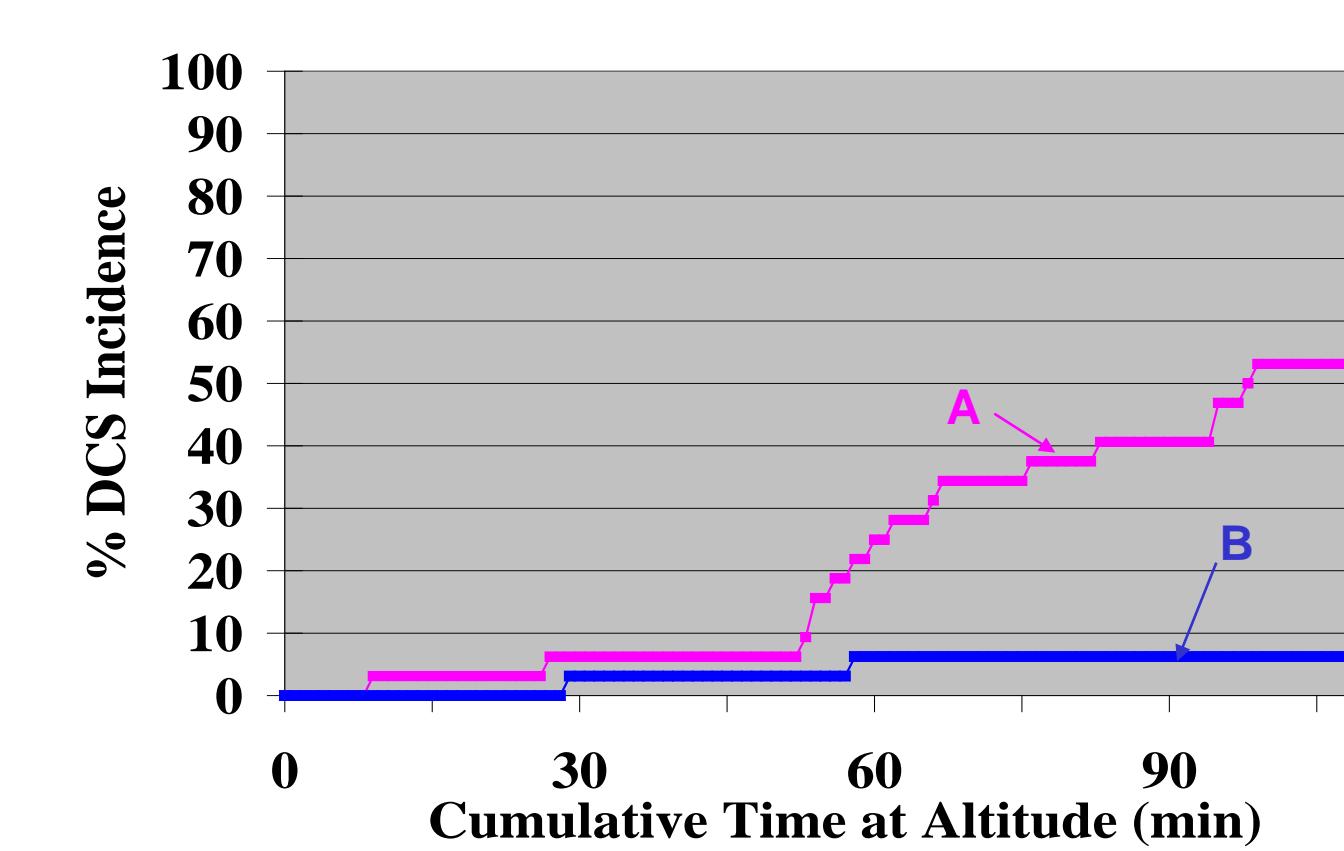


Fig. 5. The percentage of cumulative DCS onset incidence plotted vs. cumulative time at altitude for the two conditions: A (one 120-min altitude exposure with no ground-level preoxygenation) and B (four 30-min altitude exposures to the same simulated altitude, but with 1-h ground-level intervals breathing air; no prebreathing). From Pilmanis et al. (3) by permission.

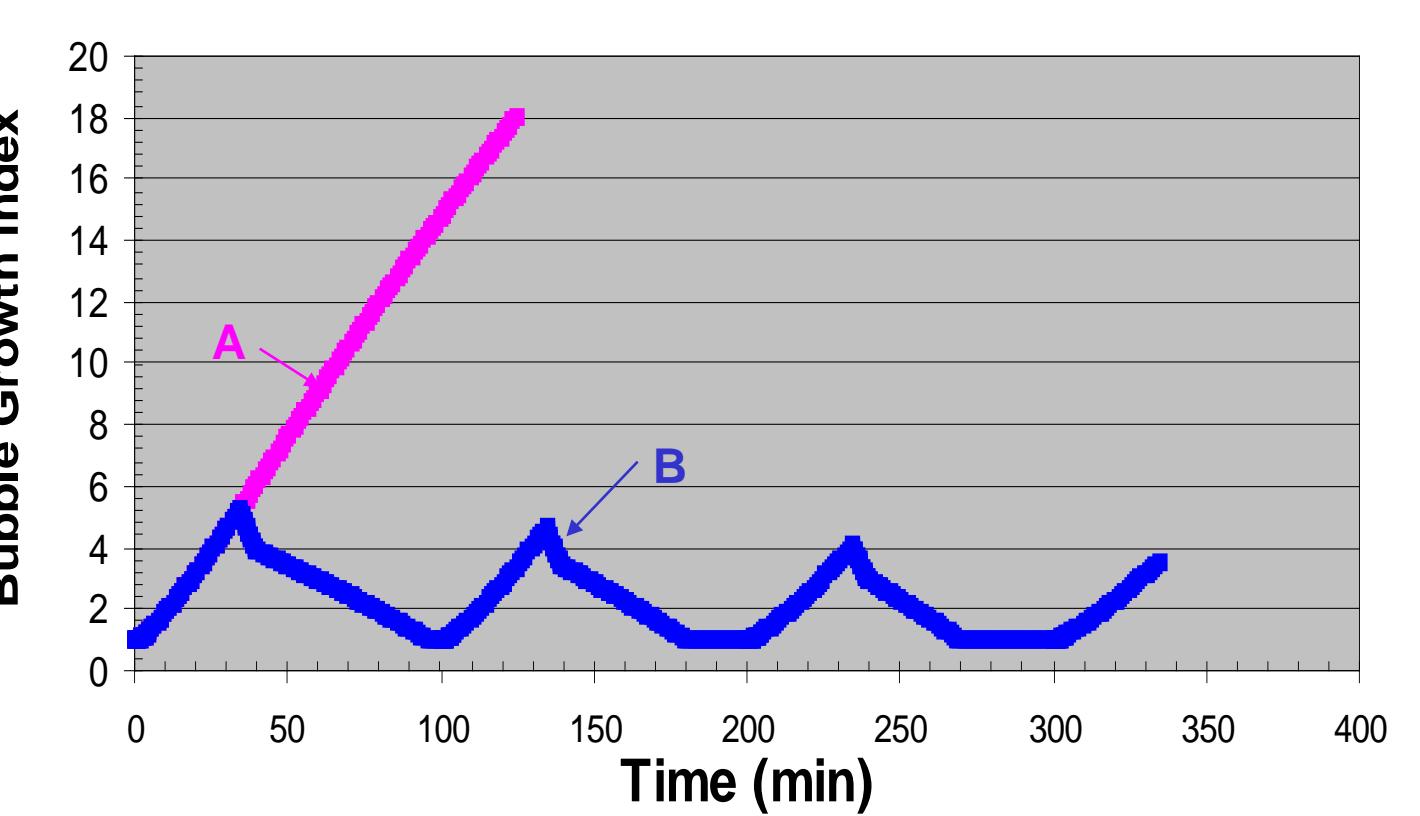


Fig. 6. The TBDM-calculated BGI for the two altitude decompression conditions described in Figure 5. The intermittent recompressions in profile B control bubble growth resulting in a maximum BGI of 5 in profile B compared with 18 in profile A. The benefits of intermittent recompression predicted by the TBDM are consistent with the observed DCS incidence in Figure 5.

DISCUSSION

- The TBDM model predicts that the benefits of intermittent recompression may enable shortening of the suit purge time with significant crew time and consumables benefits while also reducing decompression stress.

- The model indicates that intermittent recompressions reduces decompression stress by limiting the bubble growth time and size, resulting in a higher bubble to tissue diffusion gradient due to the effects of surface tension (Laplace's Law).
- EVA suits are purged of N₂ prior to depressurization to achieve $\geq 95\%$ O₂. Purge requires ~8 minutes and uses 0.65lb gas per purge per suit. In an airlock, most of this gas is reclaimed but with a suit port this gas is vented to vacuum. Thus, shortening the purge will expedite vehicle egress and save gas. A 2 min purge saves ~0.48 lb gas and 6 minutes of crew time per person per egress compared with a standard 8 min purge.

6 month mission, 4 crew, 3 egresses/day, 6 days/week:

- 900lb gas + tankage = 1800lb (819kg) per 6 months
- Over 31 hours of crew time saved per 6 months

CONCLUSIONS

- Variable pressure suits combined with the ability to perform multiple shorter EVAs may enable prebreathe protocols that save several tons of gas and hundreds of hours of crew time over the duration of the next lunar program.
- Further research is needed to characterize and optimize intermittent recompression and Nitrox breathing mixtures across the range of environments and operational conditions in which astronauts will live and work during future lunar exploration.
- Laboratory validation trials should precede operational implementation.

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